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DATE MAILED: 08/29/2008

## NOTICE OF ALLOWANCE AND FEE(S) DUE

33072 7590 08/29/2008
KAGAN BINDER, PLLC
SUITE 200, MAPLE ISLAND BUILDING
221 MAIN STREET NORTH

STILLWATER, MN 55082

EXAMINER
STROUD, JONATHAN R

ART UNIT PAPER NUMBER

3774

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/787,057	02/25/2004	Gregory H. Lambrecht	VIA-3 CON	9535
TITLE OF INVENTION: C	ARDIAC VALVE PROCEI	DURE METHODS AND DEVICES	(MTI0900/US/2)	

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$720	\$300	\$0	\$1020	12/01/2008

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 1SI. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

## HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FFE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

### PART B - FEE(S) TRANSMITTAL

# Complete and send this form, together with applicable fee(s), to: Mail Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

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appropriate. All further indicated unless corrects maintenance fee notifica	correspondence includired below or directed oth	ng the Patent, advance nerwise in Block 1, by	orders and notification of (a) specifying a new corn	maintenance fees verspondence address	vill be ; and/o	mailed to the current r (b) indicating a sepa	correspondence address as arate "FEE ADDRESS" for
CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)			Da	mers. Each additions	il paper	g can only be used fo ficate cannot be used f r, such as an assignme iling or transmission.	or domestic mailings of the for any other accompanying nt or formal drawing, must
221 MAIN STR	PLE ISLAND BUI EET NORTH		TI	Cer	rtificate	e of Mailing or Trans	mission g deposited with the United st class mail in an envelope above, or being facsimile ate indicated below.
STILLWATER,	MN 55082						(Depositor's name)
							(Signature)
			L		_		(Date)
APPLICATION NO.	FILING DATE		FIRST NAMED INVENTO	NTOR ATTORNEY DOCKET NO.		CONFIRMATION NO.	
10/787,057 02/25/2004 Gregory H. Lambrecht TITLE OF INVENTION: CARDIAC VALVE PROCEDURE METHODS AND DEVICES			ı	C	VIA-3 CON MT10900/US/2)	9535	
APPLN, TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUI	E PREV. PAID ISSU	E FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$720	\$300	\$0		\$1020	12/01/2008
EXAM	INER	ART UNIT	CLASS-SUBCLASS	7			
STROUD, JO	NATHAN R	3774	623-015000	_			
"Fee Address" ind PTO/SB/47; Rev 03-0 Number is required.  3. ASSIGNEE NAME A	ondence address (or Cha 3/122) attached. ication (or "Fee Address 12 or more recent) attach ND RESIDENCE DAT/ less an assignee is ident h in 37 CFR 3.11. Comp	nge of Correspondence "Indication form ed. Use of a Customer A TO BE PRINTED ON	THE PATENT (print or t	to 3 registered pater tively, gle firm (having as a r agent) and the nam torneys or agents. If se printed. type) patent. If an assign n assignment.	memb es of u no nan	per a 2p to 2	ocument has been filed for
Please check the appropr	iate assignee category or	categories (will not be	printed on the patent):	Individual 🗆 C	orporati	ion or other private gro	oup entity Government
4a. The following fee(s) are submitted:    Issue Fee   Publication Fee (No small entity discount permitted)   Advance Order - # of Copies			4b. Payment of Fee(s): (PI A check is enclosed Payment by credit of The Director is here overpayment, to De	ard. Form PTO-2038	is atta	ached.	shown above) ficiency, or credit any n extra copy of this form).
	s SMALL ENTITY state	is. See 37 CFR 1.27.	b. Applicant is no k				
interest as shown by the	records of the United Sta	tes Patent and Tradema	rk Office.	і ше аррисайт, а гед	istered.	amorney or agent; or tr	ne assignee or other party in
Authorized Signature				Date			
Typed or printed name				Registration N			
This collection of inform an application. Confiden submitting the complete this form and/or suggesti Box 1450, Alexandria, V Alexandria, Virginia 223	ation is required by 37 C tiality is governed by 35 d application form to the ions for reducing this but firginia 22313-1450. DC 13-1450.	FR 1.311. The informa U.S.C. 122 and 37 CF USPTO. Time will va rden, should be sent to O NOT SEND FEES OF	tion is required to obtain o R 1.14. This collection is a ry depending upon the inc the Chief Information Offi R COMPLETED FORMS	r retain a benefit by estimated to take 12 lividual case. Any co icer, U.S. Patent and TO THIS ADDRES:	the pub minuter omment Trader S. SEN	lic which is to file (and s to complete, includin ts on the amount of tir nark Office, U.S. Dep D TO: Commissioner	I by the USPTO to process) ig gathering, preparing, and me you require to complete artment of Commerce, P.O. for Patents, P.O. Box 1450,

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SUITE 200, MAPLE ISLAND BUILDING			ART UNIT	PAPER NUMBER		
221 MAIN STREET NORTH			3774			
STILLWATER, MN 55082			TO A CORE DATA AT TUDE OF COORS			

# Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 752 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 752 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

# Notice of Allowability

Application No.	Applicant(s)		
10/787,057	LAMBRECHT ET AI	L.	
Examiner	Art Unit		
Ionathan Stroud	3774		

Condition	0774
The MAILING DATE of this communication appears on t All claims being allowable, PROSECUTION ON THE MERITS IS (OR REN herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. of the Office or upon petition by the applicant. See 37 CFR 1.313 and MP	MAINS) CLOSED in this application. If not included appropriate communication will be mailed in due course. THIS This application is subject to withdrawal from issue at the initiativ
1. $\boxtimes$ This communication is responsive to <u>the amendment filed 5/22/08</u> .	
2. The allowed claim(s) is/are 2,48 and 49.	
Acknowledgment is made of a claim for foreign priority under 35 U     a)	ceived.
Applicant has THREE MONTHS FROM THE "MAILING DATE" of this conoted below. Failure to timely comply will result in ABANDONMENT of tHIS THREE-MONTH PERIOD IS NOT EXTENDABLE.	
4. A SUBSTITUTE OATH OR DECLARATION must be submitted. No INFORMAL PATENT APPLICATION (PTO-152) which gives reason	
CORRECTED DRAWINGS ( as "replacement sheets") must be sub  (a) including changes required by the Notice of Draftsperson's Pate  1) hereto or 2) to Paper No./Mail Date  (b) including changes required by the attached Examiner's Amend Paper No./Mail Date	ent Drawing Review ( PTO-948) attached
Identifying indicia such as the application number (see 37 CFR 1.84(c)) sh each sheet. Replacement sheet(s) should be labeled as such in the header	ould be written on the drawings in the front (not the back) of r according to 37 CFR 1.121(d).
DEPOSIT OF and/or INFORMATION about the deposit of BI attached Examiner's comment regarding REQUIREMENT FOR THI	
Attachment(s) 1.  Notice of References Cited (PTO-892) 2.  Notice of Draftperson's Patent Drawing Review (PTO-948) 3.  Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 2/25/04, 11/12/04, 12/14/06, 6/22/07 and	Notice of Informal Patent Application     Interview Summary (PTO-413),     Paper No./Mail Date     Examiner's Amendment/Comment
Starting Regarding Requirement for Deposit of Biological Material	Examiner's Statement of Reasons for Allowance     Other
/Thomas J Sweet/ Primary Examiner, Art Unit 3774	

U.S. Patent and Trademark Office PTOL-37 (Rev. 08-06)

Art Unit: 3774

# DETAILED ACTION

## Election/Restrictions

 Applicant's election without traverse of group III in the reply filed on 05/22/2008 is acknowledged. Applicant's arguments concerning claim 2 have been considered and are persuasive; therefore claim 2 has been included in group III and the claims to be examined. Claims 1, 3-26, 32-45 have been withdrawn.

# EXAMINER'S AMENDMENT

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mark Binder on 8/7/2008. Applicant agrees to cancel all other claims other than claims 2. 48. 49 and to amend the claims as follows:

- canceled
- (original) A method for performing an operation on a cardiac valve of a heart while the heart is beating, comprising the steps of:
- a) positioning <u>a first valve as a at-least-one</u> temporary valve in a flow path of a blood vessel <u>without affixing the temporary valve to the blood vessel and positioned</u> downstream from said cardiac valve, said temporary valve being operative to effect greater antegrade flow than retrograde flow through said vessel;
  - b) resecting at least a portion of the cardiac valve; and

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c) affixing a second valve as a at least one prosthetic valve at or downstream from said resected cardiac valve; and

d) removing the temporary valve from the flow path.

3. canceled

4. canceled

5. canceled

6. canceled

7. canceled

8. canceled

9. canceled

canceled

11. canceled

12. canceled

13. canceled

14. canceled

canceled.

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16. canceled

17. canceled

18. canceled

19. canceled

20. canceled

21. canceled

22. canceled

23. canceled

24. canceled

25. canceled

26. canceled

27. canceled

28. canceled

29. canceled

30. canceled

Art Unit: 3774

31. canceled

32. canceled

33. canceled

34. canceled

35. canceled

36. canceled

37. canceled

38. canceled

39. canceled

40. canceled

41. canceled

42. canceled

43. canceled

44. canceled

45. canceled

Art Unit: 3774

46. canceled

47. canceled

48. (currently amended)A method for enabling performance of an operation on a cardiac valve of a heart while the heart is beating, comprising the steps of:

- a) placing at least one temporary valve in a flow path of blood vessel without affixing the temporary valve to the blood vessel, said temporary valve being operative to effect greater antegrade flow than retrograde flow through said vessel; and
- b) placing at least one temporary filter in said flowpath downstream from said cardiac valve, said filter being operative to restrict the passage of emboli while allowing blood to flow through said vessel
  - resecting or disrupting at least a portion of the cardiac valve; and
  - d) removing the temporary valve from the flow path.
- 49. (currently amended)A method for performing an operation on a cardiac valve of a heart while the heart is beating, comprising the steps of:
- a) positioning <u>a first valve as a at-least-one</u> temporary valve in a flow path of blood <u>without affixing the temporary valve to the blood vessel</u>, said temporary valve being operative to effect greater antegrade flow than retrograde flow;
  - b) resecting or disrupting at least a portion of the cardiac valve; and
- affixing <u>a second valve as a at-least-one</u> prosthetic valve at, upstream or downstream from said resected cardiac valve; and
  - d) removing the temporary valve from the flow path.

Applicant agrees to amend the abstract as follows:

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The present invention discloses devices and methods for performing intravascular procedures with out:cardiac bypass. The devices include various embodiments of temporary filter devices, temporary valves, and prosthetic valves. The temporary filter devices have one or more cannulae which provide access for surgical tools for effecting repair of the cardiac valves. A cannula may have filters of various configurations encircling the distal region of the cannula, which prevent embolitic material from entering the coronary arteries and aorta.

The temporary valve devices may also have one or more cannulae which guide the insertion of the valve into the aorta. The valve devices expand in the aorta to occupy the entire flow path of the vessel. In one embodiment, the temporary valve is a disc of flexible, porous, material that acts to filter blood passing therethrough. A set of valve leaflets extend peripherally from the disc. [These leaflets can alternately collapse to prevent blood flow through the valve and extend to permit flow.

The prosthetic valves include valve fixation devices which secure the prosthetic valve to the wall of the vessel. In one embodiment, the prosthetic valves have at least one substantially rigid strut, at least two expandable fixation rings located about the circumference of the base of the apex of the valve, and one or more commissures and leaflets. The prosthetic valves are introduced into the vascular system a compressed state, advanced to the site of implantation, expanded and secured to the vessel wall.]

Applicant agrees to amend the specification as follows:

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At the first line of the specification, amend to read:

This application is:

a continuation of United States Patent Application 09/700,167, filed 11/09/2000, now patent 6.896,690, which in turn is a 371 of PCT/US/00/02126, filed 01/27/2000, which claims benefit of U.S. provisional application 60/117,599, filed 01/27/1999, and claims benefit of U.S. provisional application 60/152,135, filed 08/25/1999, and claims benefit of U.S. provisional application 60/161,934, filed 10/28/1999.

# Allowable Subject Matter

3. Claims 2, 48 and 49 are allowed. Reasons for allowance are as follows: after an extensive search of the art, claims and priority were found to predate all other existing applications of a similar nature, specifically, provisional application 60/117,599 disclosed the subject matter at hand prior to the closest available patent, Garrison 6,425,916. Specifically, the temporary nature of the temporary valve, which is implanted and subsequently removed immediately after the cardiac procedure is implemented - were found to define over the prior art in a novel and unobvious way.

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## Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN R. STROUD whose telephone number is (571)270-3070. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 6 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Isabella David can be reached on (571)272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jonathan R Stroud/ Examiner, Art Unit 3774 /Thomas J Sweet/ Primary Examiner, Art Unit 3774